Exhibit A

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ATTORNEY DOCKET NO.:INTER-5001

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing of a PROVISIONAL APPLICATION under 37 C.F.R. § 1.53(c)

INVENTORS/APPLICANTS:

Last Name	First Name	MI	Residence
Converse	Lance		
Rosenberg	Leonard		
Michelson	Leslie		

TITLE OF INVENTION: ***Method and System for Creating and Managing Databases for Clinical Trials***

CORRESPONDENCE ADDRESS:

Mary Jane Boswell
Morgan, Lewis & Bockius LLP
1800 M Street, N.W.
Washington, D.C. 20036-5869
(202) 467-7000

ENCLOSED APPLICATION PARTS: (check all that apply)

☒	Specification,	No. of Pages 11
☒	Drawings,	No. of Pages 3
☐	Claims (if any),	No. of Claims
☐	Small Entity Claim	
☐	Other (specify)	

METHOD OF PAYMENT: Check No._____ ***FILING FEE:*** $150.00

☐ A check or money order is enclosed to cover the Provisional application filing fee.

☒ The Commissioner is hereby authorized to charge deposit account no. 50-0310 to cover the Provisional application filing fee. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310.

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This invention was made by an agency of the United States or under a contract with an agency of the United States Government.

☒ No ☐ Yes (Agency/Contract No.) ______________

Respectfully submitted,

Date: January 28, 2000

MORGAN, LEWIS & BOCKIUS LLP
1800 M Street, N.W.
Washington, DC 20036-5869
(202) 467-7000

By: ______________
Mary Jane Boswell
Reg. No. 33,652

1-WA/1312867.1

UNITED STATES PROVISIONAL PATENT APPLICATION

OF

LANCE CONVERSE

LEONARD ROSENBERG

AND

LESLIE MICHELSON

FOR

METHOD AND SYSTEM FOR CREATING AND MANAGING DATABASES FOR CLINICAL TRIALS

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a method and system for creating secure databases and for using the secure databases to match pharmaceutical sponsors, clinical trial investigators, and possible patient participants over a network. The present invention includes proprietary sorting algorithms to enable appropriate parties access and use of the secure databases to conduct clinical trials.

Background of the Related Art

Advances in computer processing power and network communications have made information from a wide variety of sources available to users on computer networks. Computer networking allows network computer users to share information, software applications and hardware devices, and Internet working enables a set of physical networks to be connected into a single network, such as the Internet. Computers connected to the Internet or connected to networks other than the Internet also have access to information stored on those networks. The World Wide Web ("Web"), a hypermedia system used on the Internet, enables hypertext linking, whereby documents automatically reference or link other documents located on connected computer networks around the world. Thus, users connected to the Internet have almost instant access to information stored in relatively distant regions.

A page of information on the Web may include references to other Web pages and may include a broad range of multimedia data including textual, graphical, audio, and animation information. Currently, Internet users retrieve information from the Internet, through the Web, by "visiting" a Web site on a computer that is connected to the Internet.

A combination of technological advances in many fields, significant increases in research and development expenditures by pharmaceutical and biotechnology industry, and more demanding regulatory review by the FDA is increasing the demands for clinical trial services. With all of these increases, so too has the need for clinical sponsors, patients, and investigators increased. All parties concerned are finding it increasingly difficult to get the most current information regarding health and clinical trials that might be beneficial. Sponsors struggle to find investigators with the qualifications, experience and patient population to conduct their trials. Investigators struggle to enroll patients who meet the required inclusion/exclusion criteria. Moreover, the rapidly changing clinical environment challenges patients.

There have been advances, such as the creation of a database of physician investigators and the sites in which they conduct clinical trials. This database includes general descriptions of the trials conducted, and also historical performance metrics, coordinator experience, equipment, selected demographic and prescribing information about investigator's patient panel and health demographic data about the general population proximate to the investigator's site. This database can be accessed using decision support software designed to enable rapid identification of sites with experience, capabilities and patients necessary to perform a clinical trial. However, this database is not web enabled, and thus access is greatly limited. Moreover, the ability to supplement the database is greatly limited.

SUMMARY OF THE INVENTION

Accordingly, the present invention is directed to a method and system for creating secure databases of pharmaceutical sponsors, clinical trial investigators, and possible patient participants, and allowing access by appropriate parties to these databases over a network.

Additional features and advantages of the invention will be set forth in the description, which follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and together with the description serve to explain the principles of the invention. In the drawings:

Fig. 1 illustrates a computer network in which the inventive database creation and access may be incorporated.

Fig. 2 illustrates the TCP/IP Layering Model Protocol used during communications between components on the computer network.

Fig. 3 illustrates the inventive system for creating and managing databases for creating clinical trials.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the preferred embodiments of the present invention, examples of which are illustrated in the accompanying drawings. The present invention is described below using, as an example, an inventive method and system used over the Internet. Of course, it will be apparent to those skilled in the art that the invention is not limited to Internet use, but encompasses all network related options.

Figure 1 is an example of a local area network (LAN) 100 that is configured to utilize a non-repudiation protocol. LAN 100 comprises a server 102, four computer systems 104, 106, 108, and 110, and peripherals 112, such as printers and other devices that may be shared by components on LAN 100. Computer systems 104, 106, 108 and 110 may serve as clients for server 102 and/or as clients and/or servers for each other and/or for other components connected to LAN 100. Components on LAN 100 are preferable connected together by cable media, for example copper or fiber-optic cable and the network topology may be a token ring topology 114. It should be apparent to those of ordinary skill in the art that other media, for example, wireless media, such as optical and radio frequency, may also connect LAN 100 components. It should also be apparent that other network topologies, such as Ethernet, may be used.

Data may be transferred between components on LAN 100 in packets, i.e., blocks of data that are individually transmitted over LAN 100 to other computer networks, such as the Internet, other LANs or Wide Area Networks (WAN). Routers are hardware devices that may include a

onventional processor, memory, and separate I/O interface for each network to which it connects. Hence, components on the expanded network may share information and services with each other. In order for communications to occur between components of physically connected networks, all components on the expanded network and the routers that connect them must adhere to standard protocol. Computer networks connected to the Internet and to other networks typically use TCP/IP Layering Model Protocol. It should be noted that other Internet working protocols may be used.

As illustrated in Fig. 2, the TCP/IP Layering Model comprises an application layer (Layer 5) 202, a transport layer (Layer 4) 204, an Internet layer ((Layer 3) 206, a network interface layer (Layer 2) 208, and a physical layer (Layer 1) 210. Application layer protocols 202 specify how each software application connected to the network uses the network. Transport layer protocols 204 specify how to ensure reliable transfer among complex protocols. Internet layer protocols 206 specify the format of packets sent across the network as well as mechanisms used to forward packets from a computer through one or more routers to a final destination. Network interface layer protocols 208 specify how to organize data into frames and how a computer transmits frames over the network. Physical layer protocols 210 correspond to the basic network hardware. By using TCP/IP Layering model protocols, any component connected to the network can communicate with any other component connected directly or indirectly to one of the attached networks.

Fig. 3 illustrates the construction of the inventive system. As shown in Fig. 3, the system includes a clinical trial investigator database 305. The investigator database includes information about the doctors who perform clinical trials, such as name, address, DEA#, trial

study experiences, number of studies conducted, when studies were conducted, medical school history, etc. In addition to the raw data, this database includes a proprietary investigator rating scheme. This multidimensional rating scheme includes analyses illustrating the relative performance of the clinical trial investigator over a large number of studies, and adjustments to take into consideration potentially important contextual considerations, such as if the site was a rescue site. The investigator database, thus, includes customized database subsets that reflect the performance of specific sponsor clinical studies. Each contributing sponsor has access to the results and details of its own information. Moreover, the same aggregate information is available to other sponsors, but without the same level of detail (and without compromising confidentiality). Thus, the sponsor has access to its own historical investigator trial performance information and from "anonymous" trial performance information collected from other sponsors.

The system also includes a patient database 310. The patient database is constructed as to protect the patients' privacy, and includes information about individual patients, such as relevant clinical data, zip code of residence, and e-mail addresses. This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients.

The system also includes a sponsor database 315, which is a directory of sponsors. The sponsor database has identification and contact information regarding the sponsors. The

ventive system has a clinical trials database 325, which includes a listing of current clinical trials.

The system also includes a web site 320 through which a variety of information may be accessed through decision support software that is used to access the various databases. The web site contains a patient registry that is organized both therapeutically and geographically so that site selection decisions can be made based upon detailed knowledge of a specific patient's availability. There also are multiple Internet health care portals so that an Internet patient recruitment program that is study and site-specific can be initiated. The site includes health demographics information about the general populations proximate to an investigator's location. The web site also includes industry specific news, chat rooms related to industry specific topic and relevant clinical trials, periodic reports of results developed from patient satisfaction and outcome panels, virtual seminars on issues such as changes in FDA regulations, new categories of drugs, etc.

The web site 320 has three tiers of access. Tier 1 is available to the general public, and contains the general information about the pharmaceutical industry, industry specific news, and clinical trials. Tier 1 also contains chat rooms that will give patients a location to ask questions of research investigators and of other patients. Tier 2 is available to authorized users, such as those confirmed to be in the pharmaceutical industry. These users have access to the databases, except that the identity of investigators, site names and/or patient names are not available. This level of access also provides simple e-mail and fax tools to enable the user to start planning the investigator/patient recruitment process. Tier 3 permits access to the databases, and are generally for the sponsors of clinical trials. Through the proprietary software, tier 3 permits the sponsor

cess to the identities of the investigators, to the historic investigator trial performance information, and to means with which to communicate with both investigators and patients. Communication with patients protects the patients' privacy.

Communications between users of the web site and through e-mails are secure through authentication, encryption, remote access and digital certificates. Other methods of securing the data will be known to those skilled in the art, and are within the scope of this invention.

The system includes software that supports account sign-up, management, demographics capture, and personalization of target audiences. A core personalization and registration infrastructure supports ad-hoc user properties, profile, and behavioral data collection, content targeting, useful site and usage reporting, and specified user views. The views provide the specific information each sponsor needs, and ensures confidential and proprietary data is shielded from competitors.

The software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data.

The inventive system includes software that enables users to sort and prioritize data based on multiple criteria. For example, the inventive system software enables sponsors to produce lists of clinical trial investigators ranked by number of trials conducted in a particular therapeutic area, relative performance, health plan affiliations, prescribing behavior, etc. The inventive system software enables clinical trial investigators and sponsors to identify individuals in the patient database who have a likelihood of qualifying for a particular clinical trial and/or are

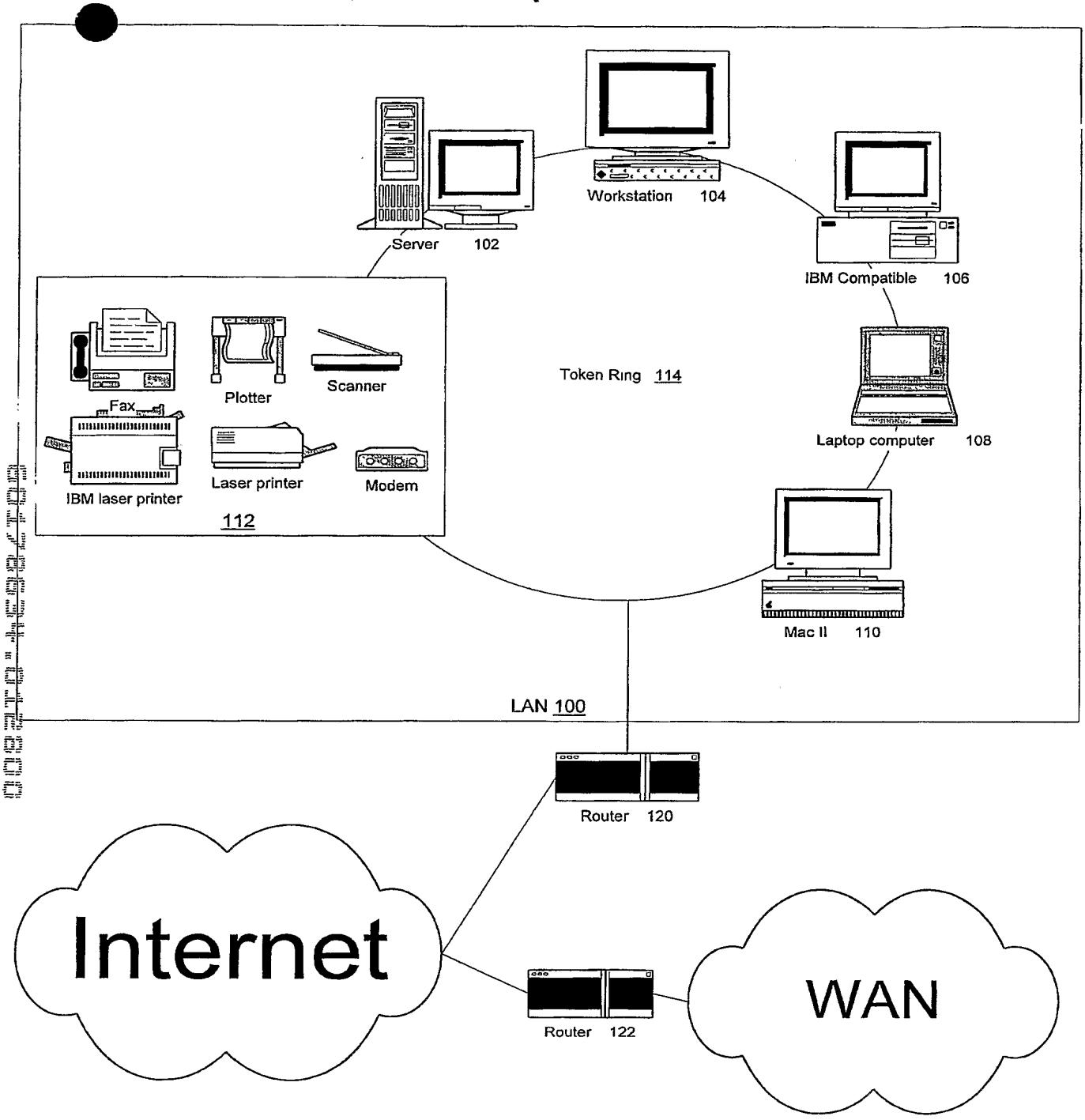
oximate to an investigator's site. Moreover, the inventive system software facilitates the communication and coordination between sponsors and clinical trial investigators relating to the budgeting, contracting, obtaining regulatory documents, and other administrative aspects initiating clinical trials. Finally, the inventive system software enables patients to identify clinical trials for which they may enroll.

With the inventive system, data sharing relationships with health care and other companies and a broad marketing and public relations campaign create large, detailed, proprietary databases of clinical trial investigators who conduct and patients who may participate in clinical trials testing the safety and efficacy of new prescription drugs. The use over the Internet, databases, investigator site selection and patient recruitment, and proprietary decision support and tracking software help the pharmaceutical and biotechnology industries accelerate the conduct of clinical trials.

It will be apparent to those skilled in the art that various modifications and variations can be made in the system and method for creating secure databases of pharmaceutical sponsors, investigators, and possible patient participants, and allowing access by appropriate parties to these databases over a network of the present invention without departing from the spirit or scope of the invention.

ABSTRACT

With the inventive system, data sharing relationships with health care and other companies and a broad marketing and public relations campaign create large, detailed, proprietary databases of clinical investigators who conduct and patients who may participate in clinical trials testing the safety and efficacy of new prescription drugs. The use over the Internet, databases, investigator site selection and patient recruitment, and proprietary decision support and tracking software help the pharmaceutical and biotechnology industries accelerate the conduct of clinical trials.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Workstation 104
IBM Compatible 106
Plotter
Scanner
Fax
Token Ring 114
Laptop computer 108
IBM laser printer
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Modem
112
Mac II 110
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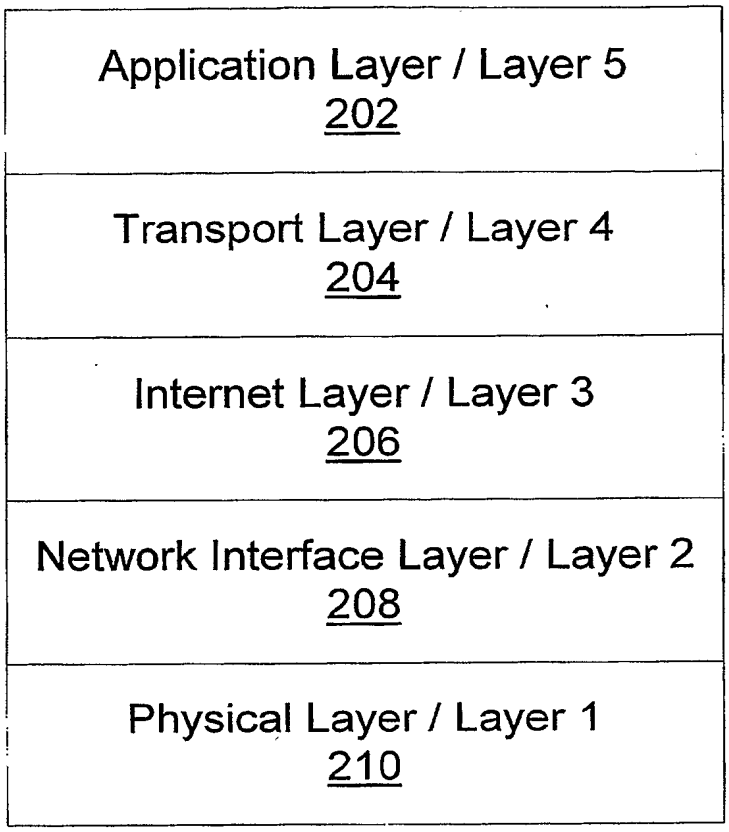
Router 120
Internet
Router 122
WAN

Fig. 1



TCP/IP Layering Model

Fig. 2

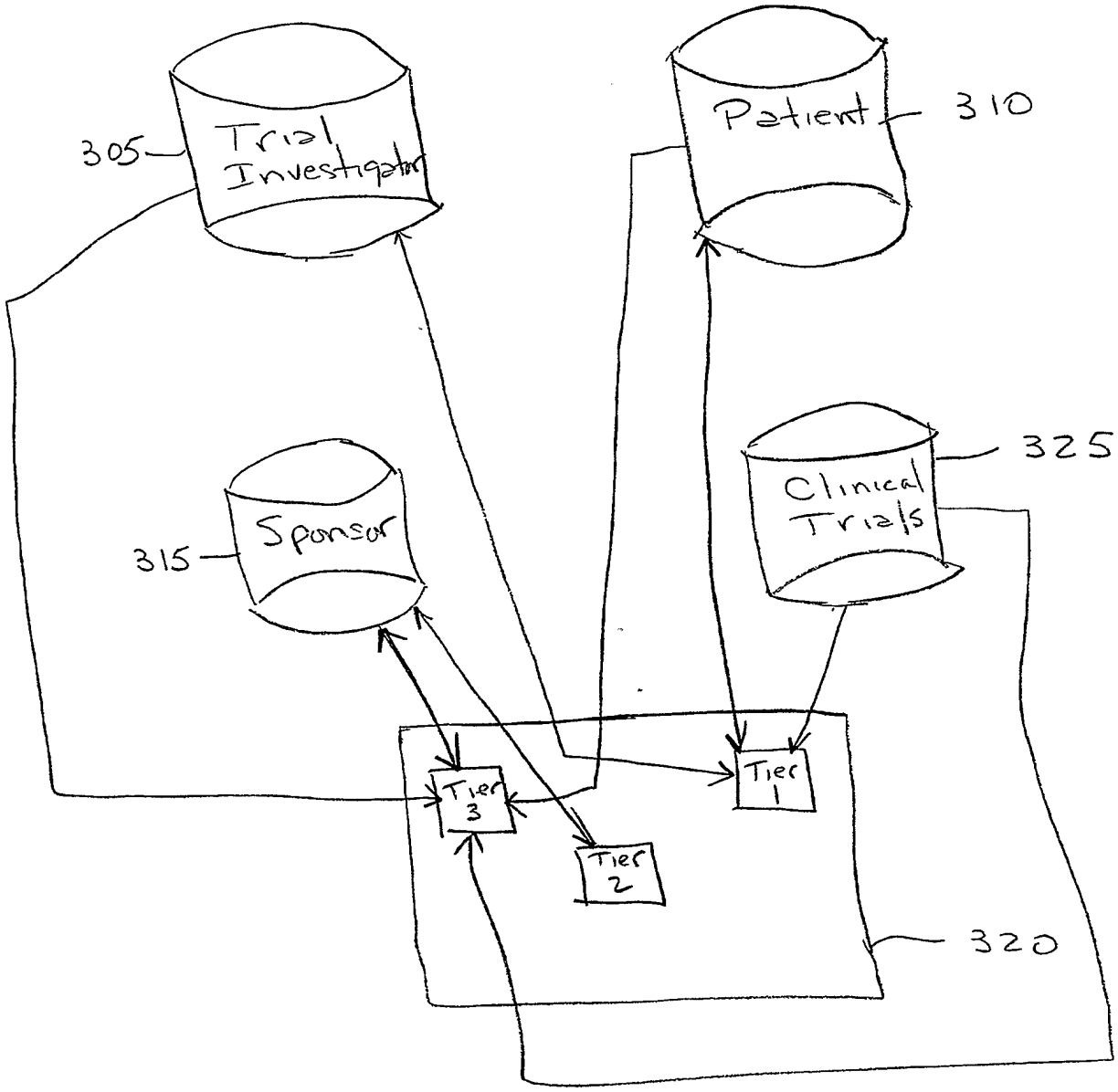

305
Trial Investigator
Patient
310
315
Sponsor
325
Clinical Trials
Tier 3
Tier 2
Tier 1
320

FIG 3